

OIE Standards on the quality of Veterinary Legislation:

Chapter 3.4 of the OIE Terrestrial Animal Health Code



OIE - AVTA - GALVMed

**REGIONAL CONFERENCE ON THE ROLE OF VETERINARY PARA-PROFESSIONALS IN AFRICA
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WORLD ORGANISATION FOR ANIMAL HEALTH
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Importance of Veterinary Legislation



“...Legislation is ***the essential function*** of modern government; it is the way that we direct and manage the complex social, economic and technological systems that constitute modern society. Legislation, therefore, is the way that we, as a people, act collectively to control and improve the world in which we live. The quality of the legislation we enact determines whether we, as a society, will prosper or decline, and possibly whether we will survive or perish...”

Edward L. Rubin - “Legislation as Policy-Making in Presidential and Parliamentary Systems” - the “Loophole”, March, 2013.

http://www.opc.gov.au/CALC/docs/Loophole/Loophole_March13.pdf

Importance of Veterinary Legislation



- Veterinary legislation provides the powers and authorities necessary for Veterinary Services to efficiently carry out their key functions to ensure public safety and promote the public good.
- In the face of growing global demand for foods of animal origin, increasing world trade, shifting patterns of disease associated with climate change and the emergence and re-emergence of diseases that can rapidly spread across international borders, ***the Veterinary Services must be supported by effective and modern legislation.***

Veterinary Legislation & the Veterinary Domain



- ***Veterinary legislation:*** means the collection of specific legal instruments (primary & secondary legislation) required for the governance of the veterinary domain.
- ***Veterinary domain:*** means all the activities that are directly or indirectly related to *animals*, their products & by-products, which help to protect, maintain & improve the health & welfare of humans, including by means of the protection of animal health & welfare & food safety.

Good Governance of the Veterinary Domain

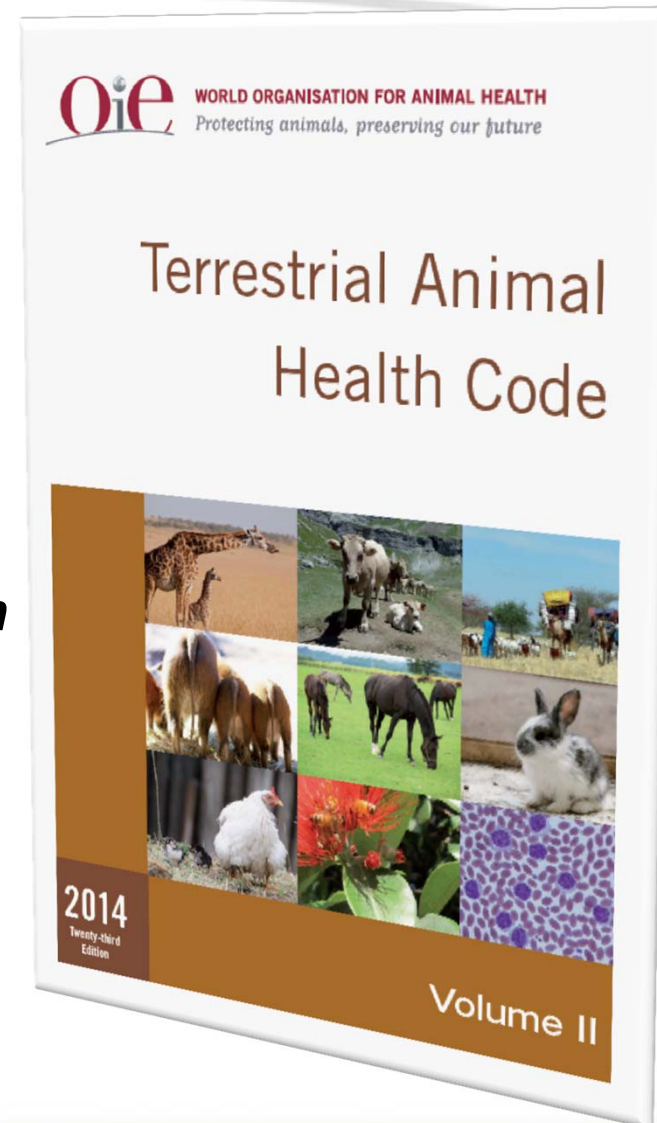


- **Good governance** is a recognised **global public good** and is of critical importance to OIE Members.
- Legislation is a key element in achieving good governance.
- Chapter 3.4 of the Terrestrial Code provides the framework for the OIE standards on veterinary legislation.
- The objective of Chapter 3.4 is **to provide advice and assistance** to OIE Members when formulating or modernising veterinary legislation so as to comply with OIE standards, thus **ensuring good governance of the entire veterinary domain**.

Brief History of Chapter 3.4



- 2010 Djerba (Tunisia) Conference Convert ***Veterinary Legislation Guidelines*** to standards in the Terrestrial Code.
- ***Ad Hoc Group on Veterinary Legislation*** developed the draft chapter on veterinary legislation.
- ***Draft chapter on veterinary legislation*** was unanimously adopted by the World Assembly of Delegates at the 80th OIE General Session in May 2012.
- ***It is now Chapter 3.4 of the OIE Terrestrial Animal Health Code***

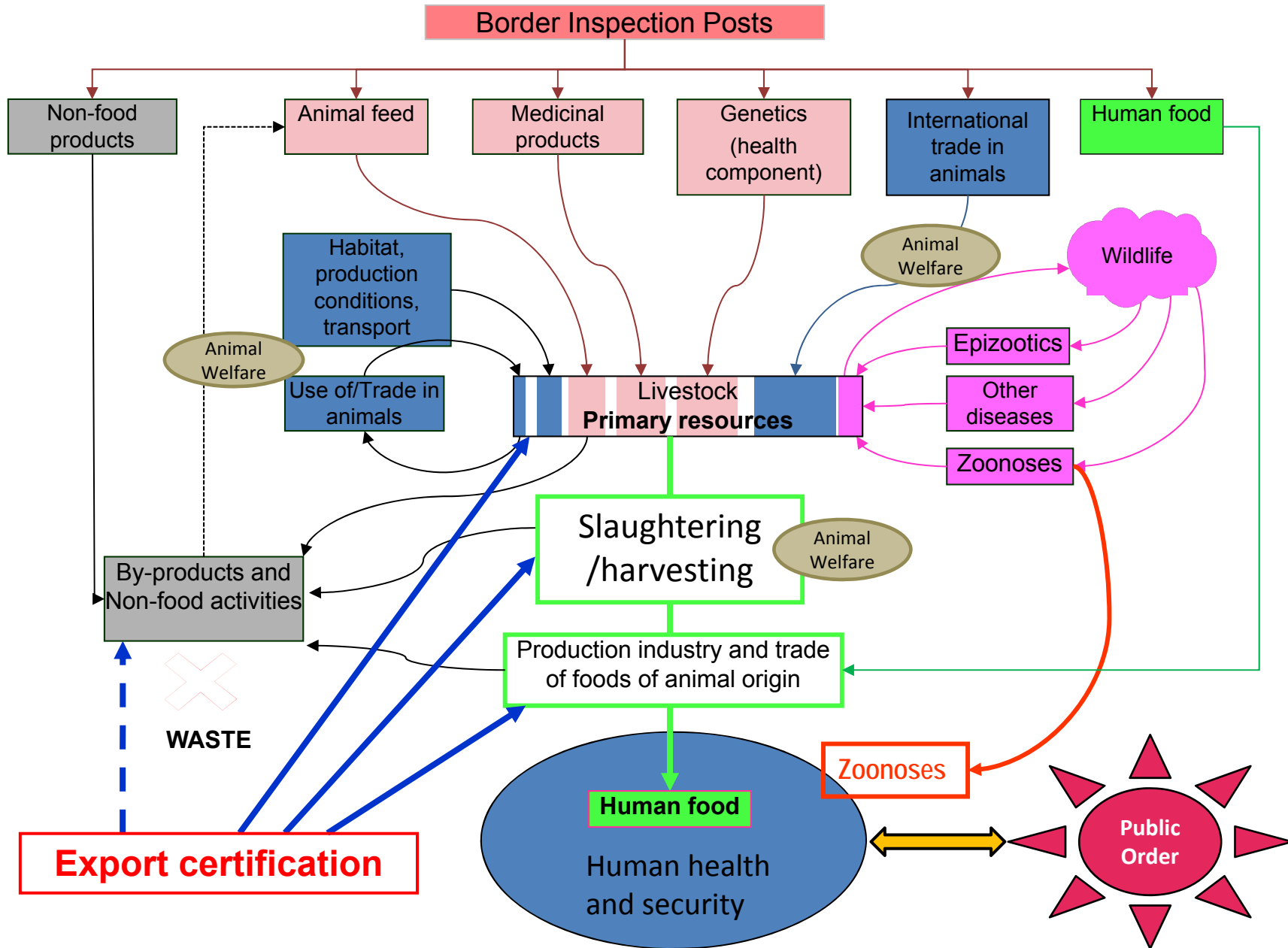


What are the Objectives of Veterinary Legislation?



- To provide a legal basis for effective **regulation of the veterinary domain** in order to achieve:
 - Food security through the protection of the primary resource (livestock health);
 - Food safety (from the farm to the fork);
 - Human health and safety (through control of dangerous animals and zoonoses);
 - Human welfare through assurance of animal welfare and animal health;
 - Safety of international trade in animals and animal products through compliance with the SPS Agreement.
 - **An enabling environment for public-private partnerships**

Cross Cutting Element: Quality Veterinary Education

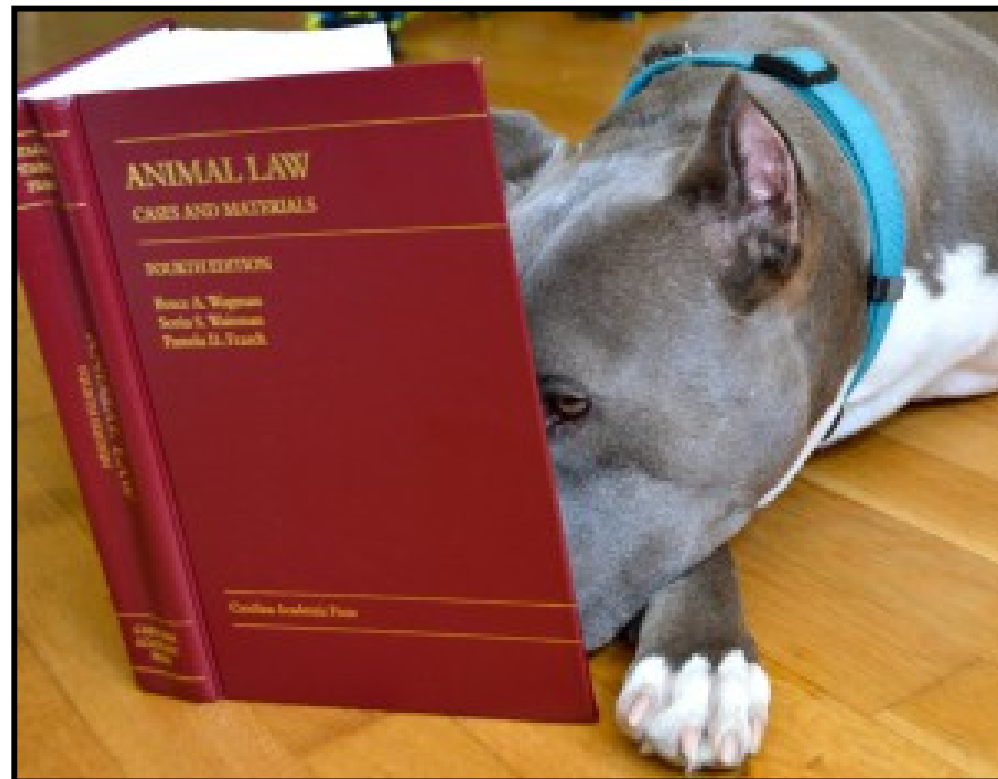


Cross Cutting Element: Effective Laboratory Services

Cross Cutting Element: Adequate Human and Financial Resources

Chapter 3.4

Veterinary Legislation



Overview of Chapter 3.4 Veterinary Legislation



General matters

- Introduction & objectives
 - Definitions
 - General principles
 - The drafting of veterinary legislation
-

Specific technical matters

- Competent authorities
- Veterinarians & veterinary para-professionals
- Laboratories in the veterinary domain
- Health provisions relating to animal production
- Animal diseases
- Animal welfare
- Veterinary medicines & biologicals
- Human food production chain
- Import & export procedures & veterinary certification

Competent Authorities



- **Competent Authorities** should be legally mandated, capacitated and organised to ensure that all necessary actions are taken quickly and coherently to address animal health and public health emergencies effectively.
- Veterinary legislation should provide for **a chain of command that is as effective as possible** (i.e. short, with all responsibilities clearly defined).
- Where **more than one Competent Authority** is involved, e.g., food safety matters, a reliable system of **coordination and cooperation** should be in place.

Delegation of Powers by the Competent Authority

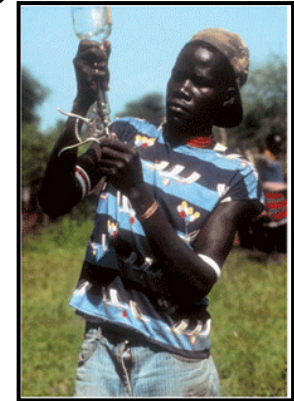


- The veterinary legislation should provide the possibility for Competent Authorities to **delegate specific tasks related to official activities to non-government actors.**
- Delegation provides the legal basis for many public-private partnerships in the veterinary domain.
- For this purpose, the veterinary legislation should:
 - define the field of activities & the specific tasks covered by the delegation;
 - provide for the control, supervision &, when appropriate, financing of the delegation;
 - define the procedures for making delegation.

Veterinarians and Veterinary Para-professionals 1



- The conduct of veterinary medicine/science
 - Set the prerogatives of veterinarians & the various categories of veterinary para-professionals to be recognized
 - Set minimum initial & continuous educational requirements & competencies for each category
 - Set conditions for recognition of their qualifications
 - Set conditions to perform the activities of veterinary medicine/science for each category
 - Identify exceptional situations where others might undertake the activities of veterinarians



Veterinarians and Veterinary Para-professionals 2



- Legislation should provide the basis for regulation:
 - Provide for the possibility of **delegation of powers** to a professional organisation, e.g., a ***veterinary statutory body (VSB)***;
 - Describe the prerogatives, the functioning & responsibilities of the mandated professional organisation (VSB).
 - Enable the VSB to establish the various categories of veterinary para-professionals to be recognised in the country;
 - Prescribe the powers to deal with conduct and competence issues, e.g., licensing requirements, penalties

Laboratories

- **Facilities** - Veterinary legislation should define the role, responsibilities, obligations & quality requirements for
 - Reference laboratories
 - laboratories designated to carry out the analysis of official samples;
 - laboratories recognised to conduct analyses required under the legislation for quality control
- **Reagents** - Veterinary legislation should provide a basis to address
 - Procedures to authorize reagents used
 - Quality assurance & surveillance of marketing



Health Provisions for Animal Production

- Legislation should provide the basis for regulation of:
 - Animal identification & traceability
 - Address all the elements in Article 4.2.3., point 6 of the Terrestrial Code, i.e., the legal framework for an animal identification system
 - Animal markets & other gatherings
 - Animal reproduction
 - Animal feed
 - Animal by-products (i.e., not for human consumption)
 - Disinfection



Animal Diseases



- Legal basis for the CA to manage diseases of importance to the country, to list those diseases & require reporting
- Surveillance
 - Legal basis to collect, transmit & utilise epidemiological data relevant to diseases listed by the *Competent Authority*
- Disease prevention & control
 - Include general animal health measures applicable to all diseases & specific measures for particular diseases
 - Provide a legal basis for exceptional powers for CA
 - Provide for the financing of animal disease control measures
 - **Delegation of official activities**
- Emerging diseases
 - measures to investigate & respond



Animal Welfare

- Veterinary legislation should provide a basis for actions to address the animal welfare-related requirements in Section 7 of the *Terrestrial Code*.
- Guiding principles for animal welfare
- **Transport** of animals by land, sea and air
- **Slaughter** of animals for human consumption
- **Killing** of animals for disease control purposes
- **Humane control of stray dog** populations
- **Use** of animals in **research and education**
- Animal welfare and **beef cattle productions systems**
- Animal welfare and **broiler chicken production systems**
- Animal welfare and **dairy cattle production systems**



Veterinary Medicines & Biologicals



- **An important area of concern relative to the rights and responsibilities of veterinary para-professionals**
- General measures
 - Definition of veterinary medicines & biologicals
 - **Provide legal basis for regulation of manufacture, importation, distribution, commerce and end use**
- Raw materials used in manufacture
 - Quality standards for raw materials used
 - Establishment of withdrawal periods & residue limits

Veterinary Medicines & Biologicals



- Quality and safety

- Conduct of clinical & non-clinical trials to verify all claims made by the manufacturer
- Conditions of trials & qualifications of experts
- Surveillance for adverse effects

- Authorisations

- Ensure that only authorised products are placed on the market including medicated feeds, compounded drugs
- Provide a basis to address **equivalence of authorisations made by other countries.**



Veterinary Medicines & Biologicals



- Establishments producing, storing and wholesaling veterinary medicines and biologicals
 - Registration of all operators along the supply chain
 - Define responsibilities and good manufacturing practices
 - Mechanisms for **traceability and recall**
- Retailing, use and traceability
 - Control of distribution with **traceability & recall**
 - Rules for **prescriptions** & provision to end users
 - Restrictions on authorisations to sell
 - Truth in advertising
 - Control on drug residues
 - Reporting of adverse effects

Human Food Production Chain



- Veterinary legislation should provide a basis for actions to **safeguard the human food production chain at all critical steps.**
- General provisions
 - Controls over all stages of the production, processing & distribution of foods of animal origin (farm to fork)
 - Recording all significant animal & public health events
 - Giving operators the primary responsibility for compliance
 - Inspection of premises for compliance of food safety standards
 - Prohibition of marketing products unfit for human consumption
 - Provisions for **traceability & recall**



Import & Export Procedures and Veterinary Certification



- Veterinary legislation should provide a basis for actions to address the elements relating to import & export procedures & veterinary certification referred to in Section 5 of the *Terrestrial Code* - Trade measures, import/export procedures & veterinary certification



Conclusions



- Veterinary legislation is necessary to provide a **legal basis for the Competent Authority** to properly and effectively regulate the veterinary domain.
- Chapter 3.4 provides advice and assistance to Member Countries when formulating or modernising veterinary legislation so as to comply with OIE standards, thus ensuring good governance of the entire veterinary domain.
- Chapter 3.4 is structured around the veterinary domain and provides an overview & checklist of the essential elements that need to be addressed in veterinary legislation.
- Effective veterinary legislation should be enabling and must directly address the roles, rights, responsibilities and obligations of veterinary para-professionals with the intention of serving the public good.

Thank you for your attention!



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